UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,353	05/02/1997	YESOOK KIM	PC9563JTJ	4835

7590 11/20/2003

GREGG C BENSON
PFIZER INC
PATENT DEPARTMENT
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/20/2003

40

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/850,353	KIM, YESOOK	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 1997* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2003 has been entered.

2. Applicant's submission affects the instant application accordingly:

(A) Claims 4-15 were previously canceled.

3. Claims 1-3 are pending in the case.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Notice of Allowance vacated

5. Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Information Disclosure Statement

6. The information disclosure statement filed September 2, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-3 rejected under 35 U.S.C. 102(a) as being anticipated by Chiesi et al (US Patent No. 5,773,029).

Applicants claims a method of locating one or more salts of a compound, said salts having a solubility in a cyclodextrin equal to or greater than a desired target solubility, comprising obtaining a series of salts of said compound, determining the equilibrium solubility of each salt in said series in an aqueous solution of said cyclodextrin, and comprising each measured solubility with said target solubility. Also claimed is a method of determining a useful salt, from within a series of salts of a particular medicinal compound, for use in making a composition of matter comprising said salt and a cyclodextrin, said method comprising (a) obtaining said series of salts; (b) determining the equilibrium solubility, in aqueous cyclodextrin solution, of each of

said salts in said series; and (c) selecting, as said useful salt, a salt in said series having a solubility in said cyclodextrin solution equal to or greater than a desired target solubility. A method further claimed involves determining a useful salt, from within a series of salts of a particular medicinal compound, for use in making a composition of matter comprising an inclusion complex of said salt in a cyclodextrin, said method comprising (a) determining a quantity of said medicinal compound required for therapeutic efficacy; (b) choosing a maximum total doe in which to administer said quantity of medicinal compound; (c) choosing a maximum total does in which to administer said quantity of medicinal compound; (c) calculating the minimum required solubility of a salt of said compound necessary to formulate said maximum total dose; (d) obtaining said series of salts; (e) determining the equilibrium solubility of each of said salts in said cyclodextrin; and (f) selecting, as said useful salt, a salt from said series having an equilibrium solubility in said cyclodextrin sufficient to permit making a total dose equal to or less than said maximum total dose.

The Chiesi et al patent discloses multicomponent inclusion complexes wherein a multicomponent inclusion complex comprises an acidic drug, a base and a cyclodextrin, wherein a complex is obtained by simultaneous salt formation and complexation. See column 2, lines 54-61 for examples of cyclodextrin derivatives that can be used in the preparation of the inclusion complexes which include alfa and gamma CD, hydroxyporpyl-βCD (HPBCD), dimethyl-βCD (DIMEB), random methylated -β-cyclodextrin (RAMED) and other cyclodextrin derivatives. In the next 2 paragraphs in this column Chiesi et al discloses that the basic component of the complexes according to the invention can be of both inorganic and organic nature, which specific examples include alkali or alkaline earth hydroxides, secondary or tertiary amines, such diethanolamine, triethanolamine, diethylamine, methylamine, trimethamine (TRS) and the like. In the first two paragraphs in column 3 Chiesi et al describes the type of acidic drugs used in the patent which is set forth to mean any drug having at least an acidic function such as a carboxy, sulfonic, sulfonylamino, sulfonylureic, phenol group and the like. Examples of classes of the acidic drugs disclosed by Chiesi et al comprises oxicams, hypoglycemic sulfonylureas, benzothiadiazine diuretics, barbturic acids,

arylacetic and arylpropionic antiinfammatory acids. See column 6, lines 57 to 62 wherein Chiesi et al describes Tables 1 and 4 as setting forth equilibrium solubility of some drugs used for the preparation of the complexes of the invention therein, wherein respective sodium salts and the physical mixture with βCD is used to determine the maximum solubility conditions at equilibrium. Also see Tables 2 and 4 wherein the instant solubility is determine for multicomponents Glibenclamide/βCD/NaOH, Glibenclamide/βCD/Diethanolamine, Piroxican/RAMEB/NaOH, and Piroxican/HPβCD /NaOH. The information set forth in Tables 1, 2 and 4 of the Chiesi et al patent allows for a comparison of the solubility properties of a series of salt, including salts of medicinal compounds as set forth in Claim 2 and salts for used to make a composition of matter comprising an inclusion complex of a salt in a cyclodextrin as set forth in Claim 3. The method described in the Chiesi et al patent for preparing multicomponent inclusion complexes anticipate the method of locating one or more salts of a compound and a method of determining a useful salt from within a series of salts as instantly claimed.

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Chiesi et al (US Patent No. 5,773,029).

Applicants claims a method of locating one or more salts of a compound, said salts having a solubility in a cyclodextrin equal to or greater than a desired target solubility, comprising obtaining a series of salts of said compound, determining the equilibrium solubility of each salt in said series in an aqueous solution of said cyclodextrin, and comprising each measured solubility with said target solubility. Also claimed is a method of determining a useful salt, from within a series of salts of a particular medicinal compound, for use in making a composition of matter comprising said salt and a cyclodextrin, said method comprising (a) obtaining said series of salts; (b) determining the equilibrium solubility, in aqueous cyclodextrin solution, of each of said salts in said series; and (c) selecting, as said useful salt, a salt in said series having a solubility in said cyclodextrin solution equal to or greater than a desired target solubility. A method further claimed involves determining a useful salt, from within a

series of salts of a particular medicinal compound, for use in making a composition of matter comprising an inclusion complex of said salt in a cyclodextrin, said method comprising (a) determining a quantity of said medicinal compound required for therapeutic efficacy; (b) choosing a maximum total doe in which to administer said quantity of medicinal compound; (c) choosing a maximum total does in which to administer said quantity of medicinal compound; (c) calculating the minimum required solubility of a salt of said compound necessary to formulate said maximum total dose; (d) obtaining said series of salts; (e) determining the equilibrium solubility of each of said salts in said cyclodextrin; and (f) selecting, as said useful salt, a salt from said series having an equilibrium solubility in said cyclodextrin sufficient to permit making a total dose equal to or less than said maximum total dose.

The Chiesi et al patent discloses multicomponent inclusion complexes wherein a multicomponent inclusion complex comprises an acidic drug, a base and a cyclodextrin, wherein a complex is obtained by simultaneous salt formation and complexation. See column 2, lines 54-61 for examples of cyclodextrin derivatives that can be used in the preparation of the inclusion complexes which include alfa and gamma CD, hydroxyporpyl-βCD (HPBCD), dimethyl-βCD (DIMEB), random methylated -β-cyclodextrin (RAMED) and other cyclodextrin derivatives. In the next 2 paragraphs in this column Chiesi et al discloses that the basic component of the complexes according to the invention can be of both inorganic and organic nature, which specific examples include alkali or alkaline earth hydroxides, secondary or tertiary amines, such diethanolamine, triethanolamine, diethylamine, methylamine, trimethamine (TRS) and the like. In the first two paragraphs in column 3 Chiesi et al describes the type of acidic drugs used in patent which is set forth to mean any drug having at least an acidic function such as a carboxy, sulfonic, sulfonylamino, sulfonylureic, phenol group and the like. Examples of classes of the acidic drugs disclosed by Chiesi et al comprises oxicams, hypoglycemic sulfonylureas, benzothiadiazine diuretics, barbturic acids, arylacetic and arylpropionic antiinfammatory acids. See column 6, lines 57 to 62 wherein Chiesi et al describes Tables 1 and 4 as setting forth equilibrium solubility of some drugs used for the preparation of the complexes of the invention therein, wherein

respective sodium salts and the physical mixture with βCD is used to determine the maximum solubility conditions at equilibrium. Also see Tables 2 and 4 wherein the instant solubility is determine for multicomponents Glibenclamide/βCD/NaOH, Glibenclamide/βCD/Diethanolamine, Piroxican/RAMEB/NaOH, and Piroxican/HPβCD /NaOH. The information set forth in Tables 1, 2 and 4 of the Chiesi et al patent allows for a comparison of the solubility properties of a series of salt, including salts of medicinal compounds as set forth in Claim 2 and salts for used to make a composition of matter comprising an inclusion complex of a salt in a cyclodextrin as set forth in Claim 3. The method described in the Chiesi et al patent for preparing multicomponent inclusion complexes anticipate the method of locating one or more salts of a compound and a method of determining a useful salt from within a series of salts as instantly claimed.

Summary

10. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White

James O. Wilson
Supervisory Primary Examiner
Technology Center 1600